



December 21, 2023

Pre-Rule Making Measure Review Committee Partnership for Quality Measurement
MMSsupport@battelle.org

RE: Feedback on Release of Measures Under Consideration List for 2023-2024 Review Cycle

On behalf of Kidney Care Partners, I want to thank the Pre-Rule Making Measure Review Committee, the Partnership for Quality Measurement (PQM), and the Centers for Medicare & Medicaid Services (CMS) for providing the kidney care community with the opportunity to review and provide comment on the 2023 Measures Under Consideration (MUC) List. Kidney Care Partners is a non-profit, non-partisan coalition of more than 30 organizations comprising patients, physicians, nurses, dialysis professionals, researchers, therapeutic innovators, transplant coordinators, and manufacturers dedicated to working together to improve the quality of care for individuals living with kidney disease.

KCP strongly supported the creation of the Medicare End Stage Renal Disease (ESRD) Quality Improvement Program (QIP). As the first truly value-based purchasing program in Medicare, the ESRD QIP has provided a foundation for the ongoing CMS efforts to expand value-based purchasing successfully within the Medicare program as a whole. KCP strengthened its commitment to value-based purchasing and rewarding high quality care when it established the broad stakeholder organization, the Kidney Care Quality Alliance, and developed several measures, many of which have been endorsed by the national consensus-based organization and adopted into Medicare quality programs during the last decade.

Given our strong support for value-based purchasing and measure development, it is important to our members that measures added to the program meet the consensus-based evaluation criteria, which requires measures to be validity and reliability, as well as actionable. We remain concerned that the "Dialysis Facility-Level ESRD Dialysis Patient Life Goals Survey (PaLS)" measure does not meet these basic elements for endorsement and, as such, is simply not ready to be considered for adoption into the Medicare program. Moreover, the patient advocates within KCP have expressed serious concerns that the measure will not only fail to provide information necessary to improve patient outcomes, but could also harm patients.

KCP supports efforts to adopt patient-reported outcomes measure, as our development of the KCP's ["Patient-Reported Outcomes for End-Stage Renal Disease: A Framework for Priorities and Measurement"](#) White Paper (KCP PRO White Paper) demonstrates. However, we have a number of serious concerns with the PaLS measure that we raised in our Spring 2023 comment letter on the measures, which as far as we can tell from the publicly available materials, have not been addressed. Moreover, when reviewed

by the consensus-based organization it was not endorsed. Therefore, KCP cannot support it being approved for use in any Medicare program.

As we noted in the Spring, the measure is a facility-level process measure assessing the percent of eligible patients in a given dialysis facility that completed at least one scorable item of the survey. However, only patient-level testing data on the survey instrument itself has been provided; there is no information provided on the facility-level process measure. We also have not seen any updated data that would address KCP's previous request for the t-score information that was based on the data collected during testing of the instrument. Nor has CMS released any data in response to its own observation that the response rate will need to be calculated *at* the dialysis facility level. Without such information, it is not possible to analyze the performance scores, reliability, or validity for the measure. A proper review of the survey's methodologic and psychometric properties is simply not possible given the data currently available.

We also note that several of our patient and patient advocate members have raised concerns about the appropriateness of tying provider reimbursement to required questioning of patients to obtain highly personal information. These members echoed patient reservations that were documented in the KCP PRO White Paper. For a PRO measure to succeed, patients must understand how the information will be used. Yet, many patient advocates continue to raise concerns about potential differential treatment based on responses to patient satisfaction and quality-of-life surveys, such as the one used in the PaLS measure. Moreover, some patient advocates also express fear that the PaLS will increase anxiety and depression among dialysis patients because recording life goals may be perceived as a step toward defining patients who are more valuable to society than others. If patients fear the survey tool, the measure will not achieve its goals, even if it were valid, reliable, and actionable.

While KCP unequivocally supports empowering patients to achieve their vision of a high-quality life, there are other measures that more appropriately address the clinical aspects of achieving health-related QOL goals. When KCP members engage with individuals who receive dialysis, these individuals focus for such measures are linked to more concrete outcomes that relate specifically to the care being provided by the facility. These factors include recovery time after dialysis, post-dialysis fatigue, cramping, nausea, lightheadedness, falls, or modality education. The KCP PRO White Paper highlighted these and other priority areas for a future kidney care patient-reported outcome measure. In addition to being focused on what patients find meaningful, these factors are also within the control of an individual's care team. These factors can be acted on and improved by dialysis facilities, whereas the goals set out in the survey are likely more a function of personal income and education than on the care being provided at a dialysis facility.

We also wish to echo comments that the Renal Support Network and the American Kidney Fund have highlighted in their work. We agree with their assessment that the use of language like "To feel like a regular person, not a person on dialysis" is insensitive and

disrespectful to those individuals who receive dialysis. Moreover, the measure seems ill-equipped to address the fact that life goals can change during different periods of time and based on different circumstances that arise. While life goal discussions are very important for care teams and individuals receiving dialysis to have, the proposed measure and its inclusion in the ESRD QIP may not be the best method to encourage those discussions.

KCP also has concerns with the lack of any detail provided on potential implementation issues, including operational issues such as the anticipated administrative burden associated with administering the survey. Likewise, patients' increasing survey fatigue given the number of survey they must already complete and potential privacy concerns with the PaLS are very real threats to validity that remain unaddressed. To address this issue, CMS could explore the integration of appropriate patient reported outcome questions into existing surveys or assessments, minimizing the burden on both patients and providers.

In addition, we are concerned that the measure would exacerbate existing health inequities by excluding many individuals who receive dialysis. The denominator currently includes only individuals able to "read and understand English", excluding a wide swath of the people who require dialysis treatments. It is also no clear why there is no exclusion for patients at the end of life or living with another terminal illness, such as n-stage cancer.

While considerable evidence highlighting the importance of patient life goals is presented in the submission materials, an association between the administration of a life goals survey with subsequent improved outcomes in the dialysis facility setting has not been demonstrated. Given the significant costs implementing the measure would require facilities to incur in terms of training, adding new data collection and data entry responsibilities, and reporting, it is important that the benefit of the measure be well established before it is adopted.

Simply put, as currently specified, the PaLS measure is simply not a good for the penalty-based ESRD QIP.

We also want to briefly mention a concern with the CKD cost measure under the MIPS program. We understand that it has been tested only at the group level, and not has not been tested at the level for which it will be implemented. As noted in our discussion about the ESRD PaLS measure, it is important that the testing information be available for stakeholders and other interested parties to review before commenting. It is not possible to analyze the measure fully without such information.

Finally, we have heard from some members a concern about the limited period of review of the MUC List measures for comment. We recognize that this timeline has been in place essentially since the beginning of the MUC List process; however, if there were an opportunity to lengthen the comment period many stakeholders would find it helpful.

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On behalf of KCP, I want to thank you for providing us with the opportunity to provide comments on the PaLS measure which is currently under review. Please do not hesitate to reach out to our counsel in Washington, Kathy Lester, if you have any questions. She can be reached at klester@lesterhealthlaw.com or 202-534-1773.

Sincerely,



John Butler
Chairman

Appendix A: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Society of Nephrology
American Society of Pediatric Nephrology
Ardelyx
AstraZeneca
Atlantic Dialysis
Baxter
Cara Therapeutics
Centers for Dialysis Care
Cormedix
CSL Vifor
DaVita
Dialysis Care Center
Dialysis Patient Citizens
Fresenius Medical Care
Greenfield Health Systems
Kidney Care Council
NATCO
Nephrology Nursing Certification Commission
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Unicycive